REMARKS

Claims 26, 33-36, 39-44 and 49 remain pending. Of these, Claims 35, 39-44 and 49 are withdrawn from consideration. Thus, Claims 26, 33-34 and 36 remain presented for further examination at this time. The Applicants respectfully request reconsideration of the patentability of these claims based on the following remarks. In addition, upon allowance of the elected claims, the withdrawn claims will be eligible for rejoinder, and such action is respectfully requested.

Anticipation

Claims 26, 33, 34 and 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Rosen et al. (U.S. Patent Application Publication No. 2002/0052308). The Examiner indicated that, although recitation of "consisting of" language in Claim 26 obviates Rosen et al. from anticipating the nucleotide sequence of SEQ ID NO: 4, the claims allegedly still read on the nucleic acid sequence of SEQ ID NO: 143 as taught by Rosen et al., which allegedly inherently encodes the amino acid sequence of SEQ ID NO: 6. However, as shown below, SEQ ID NO: 143 of Rosen et al. does not encode the amino acid sequence of SEQ ID NO: 6.

SEQ ID NO: 143 of Rosen et al. does not Encode SEQ ID NO: 6

Shown below are: 1) the nucleotide sequence of SEQ ID NO: 143, 2) the amino acid sequence encoded by 5'-3'-frame 3 of SEQ ID NO: 143, and 3) the amino acid sequence of SEQ ID NO: 6.

1. SEQ ID NO 143 (As disclosed by Rosen et al.):

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cggacggtgg gtagcggcgg cggcgctggc accccggccc cggcgggccc cggcggacgg 60
cgggcaaagg tcccaggaag gtggcgtcag catctgcagc cgcgtcgacg ttgtcggagc 120
ctccgcggag gacccaggag agccggacta ggaccagggc cctgggcctc cccacactcc 180
ccatggagaa gctggcggcc tctacagagc cccaagggcc tcggccggtc ctgggccgtg 240
agagtgtcca ggtgcccgat gaccaagact ttcgcagctt ccggtcagag tgtgaggctg 300
aggtgggctg gaacctgacc tatagcaggg ctggggtgtc tgtctgggtg caggctgtgg 360
agatggatcg gacgctgcac aagatcaagt gccggatgga gtgctgtgat gtgccagccg 420
agacactcta cgacgtccta cacgacattg agtaccgcaa gaaatgggac agcaacgtca 480
ttgagacttt tgacatcgcc cgcttgacag tcaacgctga cgtgggctat tactcctgga 540
ggtgtcccaa gcccctgaag aaccgtgatg tcatcaccct ccgctcctgg ctccccatgg 600
gcgctgatta catcattatg aactactcag tcaaacatcc caaataccca cctcggaaag 660
acttggtccg agctgtgtcc atccagacgg gctacctcat ccagagcaca gggcccaaga 720
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gctgcgtcat cacctacctg gcccaggtgg accccaaagg ctccttaccc aagtgggtgg 780
tgaataaatc ttctcagttc ctggctccca aggccatgaa gaagatgtac aaggcgtgcc 840
tcaagtaccc cgagtggaaa cagaagcacc tgcctcactt caagccgtgg ctgcacccgg 900
agcagagccc gttgccgagc ctggcgctgt cggagctgtc ggtgcagcat gcggactcac 960
tggagaacat cgacgagagc gcggtggccg agagcagaga ggagcggatg ggcggcgcgg 1020
gcggcgaggg cagcgacgac gacacctcgc tcacctgagc gycgcaccgc ttcagggacg 1080
gagacaggac cgggcgagcc ctggggcggc ggccgctcct gcactttctc ccctccccca 1140
cccggcacct ggtggcaccg ggccaggccc aggcgggtgc tgcagcctgg ctggacagag 1200
ccccaataaa cgatcccaca gcctcaaaaa aaaaa 1235

2. Amino acid sequence encoded by 5'-3'-frame 3 of SEQ ID NO: 143:

DGGStopRRRRWHPGPGGPRRTAGKGPRKVASASAAASTLSEPPRRTQESRTRTRALGLPTLP**M**
EKLAASTEPQGPRPVLGRESVQVPDDQDFRSFRSECEAEVGWNLTYSRAGVSVWVQAVEMDRTLH
KIKCRMECCDVPAETLYDVLHDIEYRKKWDSNVIETFDIARLTVNADVGYYSWRCPKPLKNRDVI
TLRSWLPMGADYIIMNYSVKHPKYPPRKDLVRAVSIQTGYLIQSTGPKSCVITYLAQVDPKGSLP
KWVVNKSSQFLAPKAMKKMYKACLKYPEWKQKHLPHFKPWLHPEQSPLPSLALSELSVQHADSLE
NIDESAVAESREERMGGAGGEGSDDDTSLTStopAXHRFRDGDRTGRALGRRPLLHFLPSPTRH
LVAPGQAQAGAAAWLDRAPINDPTASKKK

3. SEQ ID NO: 6:

MSTRAKKLRRIWRILEEEESVAGAVQTLLLRSQEGGVTSAAASTLSEPPRRTQESRTRTRALGLP
TLP**MEKLAASTEPQGPRPVLGRESVQVPDDQDFRSFRSECEAEVGWNLTYSRAGVSVWVQAVEMD**
RTLHKIKCRMECCDVPAETLYDVLHDIEYRKKWDSNVIETFDIARLTVNADVGYYSWRCPKPLKN
RDVITLRSWLPMGADYIIMNYSVKHPKYPPRKDLVRAVSIQTGYLIQSTGPKSCVITYLAQVDPK
GSLPKWVVNKSSQFLAPKAMKKMYKACLKYPEWKQKHLPHFKPWLHPEQSPLPSLALSELSVQHA
DSLENIDESAVAESREERMGGAGGEGSDDDTSLT

Referring to the amino acid sequence encoded by frame 3 of SEQ ID NO: 143 shown above, the predicted translation product is a 291 amino acid peptide (in bold). However, SEQ ID NO: 6 of the present application is 359 amino acids in length. Referring to SEQ ID NO: 6 depicted above, in addition to the 291 amino acids shown in bold, which are also encoded by SEQ ID NO: 143, there are 68 additional amino acids present upstream (identified by double and single underlining). Of these 68 amino acids, SEQ ID NO: 143 has codons that encode for the last 30 amino acids (i.e., single underlined, SAAASTLSEPPRRTQESRTRTRALGLPTLP). However, these codons are upstream from the first methionine that can be translated from SEQ

ID NO: 143 in frame 3. As such, these codons are not predicted to be translated. Moreover, SEQ ID NO: 143 does not encode the first 38 amino acids of SEQ ID NO: 6 (double-underlined). Thus, in contrast to the Examiner's assertion, SEQ ID NO: 143, as disclosed by Rosen et al. does not inherently encode the amino acid sequence of SEQ ID NO: 6.

Rosen et al. do not Teach the Presently Claimed Methods

The presently claimed methods for detecting the presence of a breast cancer cell comprise screening a subject or biological sample from the subject for the level of an expression product of a polynucleotide, wherein an elevated level of the expression product compared to a normal level of expression product when no breast cancer cells are present is indicative of the presence of a breast cancer cell. In contrast, Rosen has not shown that any of the disclosed 842 nucleic acid or polypeptide sequences are under-expressed or over-expressed in diseased tissue compared to non-diseased tissue. Rosen has merely isolated cDNA from a variety of human tissues and, in the case of SEQ ID NO: 143, indicates that this is expressed mainly in lung, colon, breast and ovarian tissue. Indeed, Rosen has not shown the expression of any polypeptide sequences, let alone a change in their expression compared to normal tissue (the Examples shown are prophetic, being written in the present tense).

Rosen teaches the tissue distribution of cDNA from various samples and lists 842 nucleic acid sequences isolated from these samples and their respective 842 encoded polypeptide sequences. Rosen then links these sequences to hundreds of diseases and disorders, such that the skilled person would not know which sequence to select, let alone be able to decide whether it would be under- or over-expressed when compared to normal tissue.

In conclusion, the Applicants have shown an increased expression of the StarD10 polypeptide in primary human breast cancers compared to normal tissue (see, Examples 12 and 13). Thus, the present invention has shown for the first time that StarDl0 is a marker of a breast cancer cell, the expression of which is increased when compared to its expression in normal tissue.

In view of the preceding remarks, the Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

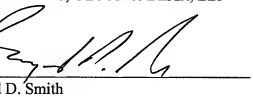
In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 31, 2009

By: 

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